

REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in view of 37 C.F.R. § 1.116, are respectfully requested. By this Amendment, claims 1-3, 7, 21-22 and 39-42 have been canceled without prejudice or disclaimer to the subject matter disclosed therein. New claims 43-50 have been added. Support for new claims 43, 44, 47 and 48 can be found, at the very least, in claim 12 as originally filed. Support for new claims 45, 46, 49 and 50 may be found, at the very least, in claims 12-14 as originally filed. No new matter has been added by the present amendment.

Entry of this Amendment is proper under 37 C.F.R. § 1.116 because the amendment places the application in condition for allowance for the reasons discussed herein; does not raise any new issue requiring further search and/or consideration because the new claims are the same as claims previously presented and searched, with the exception that they do not recite the use of γ -linolenic acid; and places the application in better form for an appeal should an appeal be necessary. Entry of the Amendment is thus respectfully requested.

Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 1-3, 6-12, 14-22, 28-37 and 39-42 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. The cancellation of claims 1-3, 7 and 39-42 render this rejection moot. Claim 6 was canceled in the Preliminary Amendment filed of February 26, 2001. In light of the cancellation of these claims,

applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 21-22 and 38 Under 35 U.S.C. §§ 102(b) or 103(a)

Claims 21-22 and 38 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by, or alternatively under 35 U.S.C. § 103(a) for purportedly being obvious over, Sigma Catalogue. Claims 21-22 and 38 have been canceled, without prejudice or disclaimer to the subject matter disclosed therein. In light of the cancellation of these claims, withdrawal of this rejection is in order and is respectfully requested.

Rejection of Claims 1-3, 6-12, 14-22, 28-37 and 39-42 Under 35 U.S.C. § 103(a)

Claims 1-3, 6-12, 14-22, 28-37 and 39-42 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Suzuki et al in view of Manoh et al and Yamaguchi et al. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The claimed invention is directed to processes for production of unsaturated fatty acids. These processes are characterized by a combination of:

- (a) the composition of inorganic ions in the medium;
- (b) the kind of producer microorganism; and
- (c) the kind of unsaturated fatty acids produced.

Each of the claims specify the different limitations of the claimed invention as follows.

In claims 8 and 9, (a) the composition of inorganic ions are defined (in claim 8, phosphate ions in the range of 5 to 60 mM, potassium ions in the range of 5 to 60 mM, sodium ions in the range of 2 to 50 mM, magnesium ions in the range of 0.5 to 9 mM and calcium ions in the range of 0.5 to 12 mM; in claim 9, phosphate ions in the range of 10 to 45 mM, potassium ions in the range of 10 to 45 mM, sodium ions in the range of 5 to 40 mM, magnesium ions in the range of 1 to 6 mM, and calcium ions in the range of 1 to 9 mM); and (b) the producer microorganism is defined as the subgenus *Mortierella*.

In claims 12 and 30, (c) the unsaturated fatty acids are defined as arachidonic acid, γ -linolenic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid.

In claims 14 and 31, (b) the producer microorganism is defined as the species *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hygrophila*.

In claims 43 and 47, (c) the unsaturated fatty acids are defined as arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid (γ -linolenic acid is excluded).

In claims 44 and 48, (c) the unsaturated fatty acid is limited to arachidonic acid.

In claims 45 and 49, (b) the producer microorganism is defined as the species *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hygrophila*; and (c) the unsaturated fatty acids are defined as arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid (again, γ -linolenic acid is excluded).

In claims 46 and 50, (b) the producer microorganism is defined as the species *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hygrophila*; and (c) the unsaturated fatty acid is limited to arachidonic acid.

Suzuki et al discloses a process for producing γ -linolenic acid in a medium. Suzuki et al does not disclose the production of arachidonic acid and other unsaturated fatty acids. The most significant difference between the present invention and Suzuki et al is the concentration of calcium ions in the culture medium. In the claimed invention, the concentration of calcium ions is 0.5 to 12 mM. As discussed on page 4 of the specification as filed, the present inventors found that it is very effective to add all of the ions of potassium, sodium, calcium, magnesium, and phosphate at defined concentrations in a well-balanced manner. Suzuki et al discloses a medium which has a concentration of calcium ions of 0.07 mM, well below the concentration of calcium ions present in the claimed invention. Therefore, Suzuki et al does not disclose or suggest the process of the claimed invention, which uses a culture medium specially formulated to maximize the yield of fatty acid production.

Furthermore, with regards to newly added claims 43-50, Suzuki et al only discloses the production of γ -linolenic acid. The claimed invention of claims 43-50 excludes the production of γ -linolenic acid. Furthermore, Suzuki et al discloses the use of *Mortierella isabellina*, *Mortierella vinacea*, *Mortierella rammaniana*, *Mortierella ramannieana* var. *Angulispora*, and *Mortierella nana*, but does not refer to *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hydrophila* of the claimed invention of claims

43-50. Therefore, the Suzuki et al reference at the very least is not relevant against the newly added claims 43-50.

Manoh et al does not solve the deficiencies of Suzuki et al. Manoh et al uses the genus *Cunninghamella* to produce γ -linolenic acid. Furthermore, Manoh et al does not disclose or suggest a preferred calcium concentration in its culture medium. In Example 3, 20 mg/l of Calcium chloride is used. This figures out to .26 mM of calcium, which is significantly less than the 0.5 to 12 mM of calcium used in the culture medium of the present invention. Therefore, Manoh et al does not disclose or suggest the claimed invention, even if taken together with Suzuki et al.

In addition, with respect to newly added claims 43-50, Manoh et al only discloses the production of γ -linolenic acid. This fatty acid is excluded from the claimed invention of claims 43-50. Therefore, even if taken in combination with Suzuki et al (which also only discloses the production of γ -linolenic acid), the combined disclosures of Suzuki et al and Manoh et al would not disclose or suggest the claimed invention of claims 43-50.

Finally, Yamaguchi et al does not disclose or suggest the claimed invention. Yamaguchi et al does not use the genus *Mortierella* nor do they produce unsaturated fatty acid. (-)trans-2,3-epoxysuccinic acid is produced by the method of Yamaguchi et al. This compound is not an unsaturated fatty acid. Therefore, this reference is not relevant to the claimed invention.

To summarize, even if the disclosures of Suzuki et al, Manoh et al and Yamaguchi et al were taken together, one would not arrive at a process for producing unsaturated fatty acids or a lipid containing them which comprises culturing a microorganism belonging to

the genus *Mortierella* in a medium containing, amongst other ions, calcium ions in the range of .5 to 12 mM. Furthermore, with respect to claims 43-50, none of the cited references disclose or suggest a method which produces unsaturated fatty acids other than γ -linolenic acid. Therefore, even if the cited references were taken together, one would not arrive at the claimed invention.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

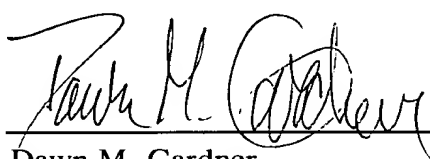
Notwithstanding the above, applicants include herewith a Notice of Appeal to avoid unintended abandonment of the above-identified application.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: May 30, 2002